

## REMARKS

Favorable reconsideration of this application is respectfully requested in view of the following remarks.

By way of this Amendment, independent Claims 1, 3 and 9 are amended, Claim 4 is canceled, and new Claims 13-18 are presented for consideration. Thus, the claims currently pending in this application are Claims 1-3 and 5-18, with Claims 1, 3 and 9 being the only independent claims.

The Official Action sets forth a rejection of independent Claims 1, 3 and 9 as being anticipated by the disclosures in U.S. Patent No. 7, 070,583 to Higuchi et al. and U.S. Patent No. 4,128,351 to Kurtz et al. In addition, the Official Action sets forth an anticipatory rejection of independent Claim 1 based on the disclosure in U.S. Patent No. 5,064,411 to Gordon, III. Those rejections are respectfully traversed for at least the following reasons.

As has been explained previously, the subject matter at issue in this application pertains to an injection needle which is specifically designed so that during use, the injection needle first contacts the skin, not by way of a point-to-point contact between the skin and the sharp needle point, but rather by way of a more linear contact between the skin 7 and a needle region that includes the needle point 5 and a portion of the curved edge (4b or 4c) projecting toward the distal end of the edge surface of the needle. Thus, as discussed at various places in the application, such as the discussion beginning in the middle portion of page 11, when the distal end of the edge surface 3 of the needle contacts the skin 7 with the edge surface 3 of the needle being forced into the skin 7, forces applied from the edge surface 3 to

the skin are distributed. This thus advantageously reduces the puncture pain associated with the injection needle penetrating the skin.

Claim 1 recites that the injection needle comprises a first ground facet formed on a distal end of a needle tube and at least two ground facets subsequently formed to provide a needle point, with the first ground facet being of a substantially elliptical shape. In addition, a plane crossing the first ground facet perpendicularly thereto and comprising the central axis of the needle tube is regarded as a central plane, with the needle point not being present on the central plane.

The rejection of independent Claim 1 in light of Higuchi et al. is based on the observation that the bevel needle disclosed in Higuchi et al. includes a needle point defined either by the intersection of the facets 5, 6 or the intersection of the facets 15, 16 (i.e., the portion of the needled identified by reference numeral 8 in Fig. 2 and reference numeral 18 in Fig. 7). Under this interpretation, it is said that the needle point is not present on the central plane.

Noting this interpretation, Claim 1 is amended to recite that the needle point which is not present on the central plane is the only needle point. Quite clearly, this is not the case with the bevel needle disclosed in Higuchi et al. as the disclosed bevel needle includes several other needle points. In addition, one of the other needle points (i.e., the needle point defined at the intersection of the facets 5, 5 or the facets 15, 15) is located on the central plane. Thus, Higuchi et al. lacks disclosure of only one needle point not present on the central plane.

This same observation also applies with respect to the medical device disclosed in Gordon, III which includes two needle points 18, 18. Thus, Gordon, III also lacks disclosure of only one needle point not present on the central plane.

It is thus respectfully submitted that independent Claim 1 is patentably distinguishable over the disclosures in Higuchi et al. and Gordon, III.

Independent Claims 3 and 9 are also amended to recite that the claimed needle point is the only needle point, once again distinguishing over the disclosure in Higuchi et al.

With respect to Kurtz et al., this document discloses a sternotomy surgical needle that includes a main cutting edge 58 formed by the intersection of first and second surfaces 60, 62, as well as a third surface 72. In addition, Kurtz et al. illustrates in Figs. 3 and 4, and describes in lines 55-59 of column 4, that the needle is provided with a flat section 84 forming a needle holder which allows a user to hold the needle.

The Official Action observes that the flat section 84 of the surgical needle disclosed in Kurtz et al. corresponds to the first ground facet recited in independent Claim 1. However, the flat section 84 forming the needle holder in Kurtz et al. is not of a substantially elliptical shape as recited in independent Claim 1. In addition, Claim 1 recites that a plane crossing the first ground facet perpendicularly thereto and comprising the central axis of the needle tube forms a central plane, wherein the needle point is not present on such central plane. As shown in the attached annotated version of Fig. 3 of Kurtz et al., the central plane (marked "X") which crosses the flat section 84 (i.e., the first ground facet) perpendicularly thereto and comprises the central axis of the needle tube passes through the needle point 66. That is, the needle point 66 in Kurtz et al. is present on the central plane that crosses the flat section 84 perpendicularly thereto and comprises the central axis of the needle tube.

The Official Action does not address this point, other than to quote the claim language and state that Kurtz et al. discloses the claimed subject matter. It is respectfully submitted that Kurtz et al. is lacking both with respect to the claimed substantially elliptical shape of the first ground facet and the fact that the flat surface 84 is present on the central plane. In the event the Examiner continues to believe that the disclosure in Kurtz et al. is relevant to the claimed injection needle recited in Claim 1, the Examiner is kindly asked to provide explanation on these points.

Independent claim 3 recites that the injection needle comprises, together with the other claimed features, first, second and third ground facets, including an angle  $\alpha$  between the first ground facet and the central axis of the needle point, an angle  $\Phi$  between the second ground facet and the central axis of the needle point, and an angle  $\theta$  between the third ground facet and the central axis of the needle point, wherein  $\alpha < \Phi$ ,  $\alpha < \theta$ , and  $\Phi \neq \theta$ . Noting the curved nature of the needle disclosed in Kurtz et al. and the associated arrangement of the central axis, it is not at all clear how it can be said that Kurtz et al. satisfies the claimed relationship set forth in Claim 3. Clarification on this point in the next Official Action is respectfully requested.

In addition, Claim 3 is amended to recite the central plane, and to define that the minimum distance between the needle point and the central plane is in the range set forth in Claim 3. Considering that the needle point 66 in Kurtz et al. is located on the central plane, Kurtz et al. cannot be said to disclose the minimum distance between the needle point and the central plane as set forth in Claim 3.

Claim 9 recites an injection needle produced by a method comprising grinding the distal end portion of the needle tube to form a first ground facet, and grinding such first ground facet to form at least second and third ground facets providing a

needle point, wherein the needle point is not present on a central plane crossing the first ground facet perpendicularly thereto and comprising a central axis of the needle tube. Once again, as noted previously, the needle point 66 in Kurtz et al. is located on the central plane. In addition, in Kurtz et al., the disclosed needle is not produced by a method involving grinding the distal end portion of a needle tube to form a first ground facet, and grinding such first ground facet to form at least second and third ground facets. This difference in the way in which the needles are fabricated results in a structural difference. In Kurtz et al., the facets 60, 72 are not formed by grinding a portion of the flat surface 84 (first ground facet) and so the facets 60, 72 are provided at the distal end of the needle, whereas the flat surface forming the needle holder is spaced proximally. This is structurally different from the structure that results from grinding the distal end portion of a needle tube to form a first ground facet, and grinding such first ground facet to form at least second and third ground facets.

It is thus respectfully submitted that independent Claims 1, 3 and 9 are patentably distinguishable over the disclosure in Kurtz et al.

Submitted with this Amendment are new dependent Claims 13-18 defining additional aspects of the claimed injection needle. For example, Claims 13, 15 and 17 define that the needle point is not present on the major axis of the substantially elliptically-shaped first ground facet as described in lines 11-16 on page 11 of the present application. Such a feature is not disclosed in Kurtz et al.

Also, new Claims 14, 16 and 18 are added to recite that the central plane intersects the distal end region of the curved outer edge of one of the second and third ground facets. These claims are added in the event the rejection based on

Kurtz et al. is premised on a currently unapparent interpretation of the central plane.

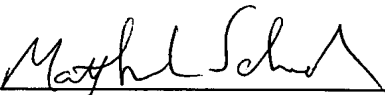
Early and favorable action with respect to this application is respectfully requested.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference with the undersigned would be helpful in resolving any remaining issues pertaining to this application the undersigned respectfully requests that he be contacted at the number indicated below.

Respectfully submitted,

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